IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

UNITED STATES OF AMERICA
ex rel. KEVIN GRAY **PLAINTIFF**

v. **NO.: 3:15-CV-127-MPM-JMV**

MITIAS ORTHOPAEDICS, PLLC,
AND HANNA M. MITIAS, M.D. **DEFENDANTS**

ORDER

This matter is the court on Defendants' Amended Joint Motion to Compel a 30(b)(6) Deposition of the Federal Drug Administration ("FDA") to give deposition testimony on certain topics [154]. For the reasons discussed below, the motion is granted in part and denied in part.

Discussion

The instant motion seeks to compel an FDA representative to address three general topics, each of which includes multiple subtopics. The three general topics are: (1) The FDA's interactions with U.S. Compounding in or around 2015 related to the manufacture, production and distribution of hyaluronic acid to medical providers; (2) the FDA's oversight of any 503B outsourcing facility that was reporting the manufacture and distribution of hyaluronic acid mixed with lidocaine from 2008-2014; and (3) the FDA's evaluation of whether hyaluronic acid used to treat osteoarthritis of the knee meets the definition of a medical device. The Government asserts generally that the information sought is not discoverable.

In the undersigned's view, because discoverable information is that which is relevant to a claim or defense at issue in the case, it is necessary to first determine what these claims and defenses are in order to resolve the instant discovery dispute. This seemingly simple assessment however is complicated by a number of material changes to the specific acts of wrongdoing

complained of over the course of the six-year pendency of this action, all as evidenced by the amended pleadings and representations regarding the same made in briefing.

For example, when this action was filed by Relator in 2015, it was asserted that the wrongful conduct complained of (aside from some service-related matters not relevant here) was the alleged use of compounded hyaluronic acid for treatment of osteoarthritis of the knee. According to the complaint, the use of compounded hyaluronic acid was a dangerous, illegal, and non-reimbursable event, for which the Defendant improperly billed Medicare by representing the product utilized to have actually been a brand name hyaluronic acid approved by the FDA. Approximately 5 years later, the Government elected to intervene and in their complaint reiterated the Relator's claims that the hyaluronic product at issue was not FDA approved, as were eight name brand hyaluronic acid products, and that because compounded hyaluronic acid was a "device" rather than a drug, it had to be FDA approved in order for a provider, such as the Defendants, to administer the same to patients and seek reimbursement for the product by the government. Further, the Government asserted that because the compounded hyaluronic acid at issue was a "device" and was not FDA approved, it was deemed a misbranded and adulterated product.

Then, on June 18, 2021, the Government filed its first amended complaint, and of relevance here, left only a single reference to the word "device," omitting, entirely, according to repeated representations in briefing and in open court, that the claim that compounded hyaluronic acid was a "device" and as such had to have FDA approval for use and reimbursement, was abandoned. The Defendants have denied any wrongdoing in response to the first amended complaint, but assert in the alternative, that even if they submitted billings intended only for approved brand name hyaluronic acid products, they are nevertheless entitled to a credit or offset for the amount of

reimbursement they would have received if they had sought reimbursement for the compounded hyaluronic acid under the miscellaneous "J" code, J3490. The Government now concedes this code allows for reimbursement to a provider for administration of a compounded hyaluronic acid to patients.

Shortly after the first amended complaint was filed, the Defendants noticed and took the 30(b)(6) deposition of CMS, the government agency responsible for responding to provider requests for reimbursement of products administered to, among others, Medicare eligible patients. Promptly thereafter, the Defendants noticed the instant motion to compel the 30(b)(6) of the FDA.

In the briefing in response to the motion, the Government asserts that much of the discovery sought from the FDA is not relevant because the conduct complained of, and for which damages are sought, has been significantly narrowed since this action was filed. Specifically, the Government represents that it has "abandoned" its theory that: (1) "FDA-approval is a requirement for reimbursement of compounded Hyaluronic Acid Products"; (2) "FDA's classification of the Hyaluronic Acid Products has any impact on coding or reimbursement"; (3) any contention that "there is anything inherently wrong with the purchase, use, or even billing of compounded HA Products (if done correctly)"; (4) any claim that the compounded hyaluronic acid at issue in this case was "misbranded or adulterated"; and (5) any claim that compounded hyaluronic acid was "*per se* non-reimbursable." *See* Pls.' Resp. in Opp'n at 3-4. [167].

According to the Government, what is left of its claims (aside from certain claims concerning services not relevant here) "is a straightforward case about whether Defendants knowingly used a billing code for a product that was not covered by that billing code." *Id.* at 2. Consistent with its assertion that the claim has thus narrowed, the Government asserts with respect to the deposition of the FDA, that: (1) the "FDA does not process or pay claims to Federal Health

Programs for reimbursement, nor does it promulgate payment rules"; the CMS [not FDA] "determines when and how to assign billing codes, how much to reimburse under the code and when to reimburse"; and "there is no testimony that FDA can give that would change Defendants' billing obligation or CMS's reimbursement decision for the Hyaluronic Acid Products." *Id.* at 3. In short, the Government represents that because it has abandoned its theory that there's anything inherently wrong with the purchase, use or even billing of compounded hyaluronic acid, if done correctly, there is no need to discover how FDA investigated or engaged with compound pharmacies who supplied providers with compounded hyaluronic acid, subjects addressed in 30(b)(6) general topics 1 and 2 described above.

On the other hand, the court notes that, according to the Government, FDA product approval is a signal to CMS that the product is "safe and effective," and being "safe and effective" is one of the statutorily mandated factors to establish that the product is "reasonable and necessary" so as to ever be reimbursable under Medicare. *Id.* at 3-4. Moreover, according to the 30(b)(6) designee of CMS (who also serves as a designated expert for the Government), it is the FDA, not CMS, who would make the determination that the compounded hyaluronic acid in this case was safe and effective so as to qualify for reimbursement under the miscellaneous J code referenced above. Specifically, the CMS 30(b)(6) designee, Dr. Perez-Schaening testified:

> Q: So let's assume that a pharmacy is compounding hyaluronic acid in a manner that is in compliance with the Food, Drug and Cosmetic Act.
> A: Uh-huh.
>
> Q: CMS has not told the MAC that it should not pay for that compound from that pharmacy and someone submits a claim on using HCPCS Code J3490 and they identify that product and provide the invoice.
> A: Uh-huh.
>
> Q: That is a covered reimbursable claim, it is not?

> A: It could be denied.
>
> Q: On what basis?
> A: Because, as I say, payment is not coverage. Coverage, you have to evaluate that it is reasonable and necessary for a particular patient.
>
> Defs.' Reply at 2; (internal citations omitted). [174]

According to Dr. Schaening-Perez, "one of the criteria of reasonable and necessary is that the agent is deemed safe and effective." *Id.* at 2-3. When asked if he deemed the compounded hyaluronic acid from U.S. Compounding as dangerous, Dr. Schaening-Perez said that he "did not deem it safe and effective." *Id.* at 3. Dr. Schaening-Perez testified that, aside from unusual circumstances not relevant here, the FDA would have to determine that the compounded product was safe and effective. "[I]t wouldn't be done by me. It would be a - - FDA, one of their - - their inspections." *Id.*

In view of the foregoing, the undersigned is persuaded that although the Defendants have not demonstrated how the FDA's testimony would be relevant on what the Government describes as its only remaining claim of wrongdoing – the simple issue of whether Defendants, with the requisite scienter, billed the Government for reimbursement of a product they did not administer – the Defendants have demonstrated a need to inquire of the FDA on general topics 1 and 2 (including subparts) in so far as those subjects relate to the safety and effectiveness of the compounded hyaluronic acid at issue in this case. This is relevant because, as noted, Defendants assert that, even if they incorrectly billed for the administration of compounded hyaluronic acid under the wrong code, they could have billed for the compounded hyaluronic acid, and been reimbursed for it under Code J3490, entitling them to an offset against any monies found to be owed as result of the alleged incorrect billing.

In conclusion, given this recent testimony of the Government's expert and the CMS 30(b)(6) designee, Dr. Schaening-Perez, the topics that concern FDA's view or position with respect to the safety and effectiveness of the compounded hyaluronic acid in this case are relevant on an issue that is alive in the case and thus properly the subject of discovery. Accordingly, the court orders that the Defendants may inquire of the FDA on general topics 1 and 2 specified above, including their subtopics, but limited to the extent these subjects relate to or concern the safety and effectiveness of the subject compounded hyaluronic acid. Except as granted, the motion is denied.

SO ORDERED, this, the 26th day of August, 2021.

/s/ Jane M. Virden
UNITED STATES MAGISTRATE JUDGE